

## 1. AMENDMENTS

Claim 10 has been amended to recite that the composition of the invention comprises a specifically enumerated compound selected from the group consisting of dihydro-isohumulone, dihydro-isocohumulone, dihydro-isoadhumulone, tetrahydro-isohumulone, tetrahydro-isocohumulone, tetrahydro-isoadhumulone, hexahydro-isohumulone, hexahydro-isocohumulone, and hexahydro-isoadhumulone and a curcuminoid. Support for the specifically enumerated compounds may be found through the specification as a whole and in currently canceled Claim 21.

Claim 17 has been canceled without prejudice wherein the Applicants reserve the right to pursue protection for other compounds appearing in this claim.

Claim 21 has been canceled and specifically enumerated compounds have been incorporated into currently amended Claim 16. The Applicants reserve the right to pursue protection for other compounds appearing in this claim.

Claims 23, and 25 – 29 have been amended to reflect the specifically enumerated compounds of currently amended Claim 16.

Claim 32 has been amended to reflect proper claim dependency in light of the claim amendments presented herein.

Applicants respectfully request reexamination and reconsideration in light of the following remarks.

**II. CLAIM REJECTIONS UNDER 35 USC § 102**

Claims 16, 17, 21, 22, 25 and 29-32 stand rejected under 35 USC § 102(e) as being anticipated by Babish, et al. (US 2003/0096027 A1, hereinafter "Babish").

The Applicants respectfully traverse.

As shown in the enclosed Declaration of Dennis Emma, Applicants respectfully submit that 'Babish' is not an invention "by another" and therefore is not a prior art reference to this application. As such, the Applicants respectfully request withdrawal of the rejection.

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Claims 16, 17, 22, 30 and 31 stand rejected under 35 USC § 102(e) as being anticipated by Newmark et al (US 6,391,346 B1; hereinafter "Newmark").

The Office cites Newmark as teaching an oral composition comprising 7% curcumin, 35% humulones, 12% lupulones, and 1.5% xanthohumol in a pharmaceutical carrier, and that the composition preferably contains a supercritical carbon dioxide extract of hops. The Applicants respectfully traverse.

To be anticipatory, a prior art reference must teach (either explicitly or implicitly) all of the elements and limitations of a disputed claim. The Applicants maintain that Newmark is not anticipatory to the claims as currently amended. Newmark does not teach a composition comprising a curcuminoid and the specifically enumerated reduced isalpha acids of amended Claim 16.

Further, Newmark does not teach that these components are present or used in synergistic, anti-inflammatory effective amounts nor that these components in the composition have a combination index less than one.

As such, the Applicants maintain that Newmark is not anticipatory to the instant case and respectfully request withdrawal of the rejection of Claims 16, 17, 22, 30 and 31 under 35 USC § 102(e) as being anticipated by Newmark et al (US 6,391,346 B1)

### **III. CLAIM REJECTIONS UNDER 35 USC § 103**

Claims 23, 24 and 26-29 stand rejected under 35 USC § 103(a) as being obvious over Babish, et al. (US 2003/0096027 A1, hereinafter "Babish").

The Applicants respectfully traverse.

As shown in the enclosed Declaration of Dennis Emma, Applicants respectfully submit that 'Babish' is not an invention "by another" and therefore is not a prior art reference to this application. As such, the Applicants respectfully request withdrawal of the rejection.

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Claims 21 and 23-29 stand rejected under 35 USC § 103(a) as being obvious over Newmark, et al (US 6,391,346 B1; hereinafter "Newmark") as applied to Claims 16, 22, 30 and 31 in view of Klusters (US 4,758,445; hereinafter; "Klusters").

The Office states that Newmark does not teach isovalpha acids or the specific compounds of claim 21. Newmark also does not teach the specific ranges of the fraction isolated from hops, or the ratio between the fraction isolated from hops and the curcuminoid.

The Office further cites Klusters as teaching that hop extracts obtained by extracting hops with supercritical carbon dioxide contains isovalpha acids such as trans-isohumulones.

The Office maintains that it would have been obvious to one of skill in the art to combine the composition of Newmark and isovalpha acids or the specific compounds of claim 21 and Klusters to produce the instant invention. The Applicants respectfully traverse.

The Applicants maintain that Newmark, in view of Klusters, does not render the instant case obvious in view of the claims as currently amended. Neither Newmark nor Klusters teach

or suggest a composition comprising a curcuminoid and the specifically enumerated reduced isosalpha acids of amended Claim 16 where these components are present or used in synergistic, anti-inflammatory effective amounts nor that these components in the composition have a combination index less than one. The identification of specific amounts of components within the synergistic ratios identified (see, for example, Example 3 and Figures 6A-H) is an unexpected result that could not have been predicted by the teachings of either Newmark or Klusters nor could such results be expected to be observed as part of the "routine experimentation" necessary to optimize the composition. Such unexpected results are per se unobvious. As such, a person of ordinary skill in the art could not have predicted the present invention as claimed nor could have had any expectation of success to modify the teachings of Newmark and Klusters to arrive at the composition presently claimed.

Applicants respectfully request the withdrawal of the rejection of Claims 21 and 23-29 under 35 USC § 103(a) as being obvious over Newmark, et al (US 6,391,346 B1; as applied to Claims 16, 22, 30 and 31 in view of Klusters (US 4,758,445).

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Claims 1 and 32 stand rejected under 35 USC § 103(a) as being obvious over Heng (WO 00/70949 A1; hereinafter "Heng") in view of Beiersdorf (WO 03/003997 A3; hereinafter "Beiersdorf").

The Office cites Heng as teaching a composition and method comprising curcumin and an anti-inflammatory drug to treat inflammatory diseases noting that Heng does not teach a fraction derived from hops. The Office further cites Beiersdorf as teaching that hops extracts are used to treat inflammatory conditions.

The Office maintains that it would have been obvious to one of skill in the art to combine the teachings of Heng and Beiersdorf to produce the anti-inflammatory compositions and methods of the instant case. The Applicants respectfully traverse.

The Applicants maintain that Heng, in view of Beiersdorf, does not render the instant case obvious in view of the claims as currently amended. Neither Heng nor Beiersdorf teach or suggest a composition comprising a curcuminoid and the specifically enumerated reduced isosalpha acids of amended Claim 16 where these components are present or used in synergistic,

anti-inflammatory effective amounts nor that these components in the composition have a combination index less than one. The identification of specific amounts of components within the synergistic ratios identified (see, for example, Example 3 and Figures 6A-H) is an unexpected result that could not have been predicted by the teachings of either Heng or Beiersdorf nor could such results be expected to be observed as part of the "routine experimentation" necessary to optimize the composition. Such unexpected results are per se unobvious. As such, a person of ordinary skill in the art could not have predicted the present invention as claimed nor could have had any expectation of success to modify the teachings of Heng and Beiersdorf to arrive at the composition presently claimed.

Applicants respectfully request the withdrawal of the rejection of Claims 1 and 32 under 35 USC § 103(a) as being over Heng (WO 00/70949 A1) in view of Beiersdorf (WO 03/003997 A3).

#### **IV. CONCLUSION**

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended Claims 16, 17, and 21-32 are in condition for allowance. Passage to issue is respectfully requested.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Office is requested to call Applicant's agent at the telephone number shown below. The commissioner is hereby authorized to charge any fees required in connection with filing of this paper to our Deposit Account 50-1133.

A Request for a Three (3) Month Extension of Time, up to and including December 29, 2010 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(3), the Office is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,

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